



SYBRON DENTAL SPECIALTIES

K110376

APR - 5 2011

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
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Wendy Garman - Contact Person

Date Summary Prepared: January 2011

Device Name:

- Trade Name – *Impression Compound*
- Common Name – Impression Material
- Classification Name – Impression Material, per 21 CFR § 872.3660

Device for Which Substantial Equivalence is Claimed:

- GC America Incorporated, *ISO Functional*, K022430

Device Description:

Impression Compound is a thermoplastic impression material available in cakes for full or partial impressions or in sticks for adding to the periphery of an impression or for copper band impressions. Impression Compound is available in three different working temperatures. The different colors signify the softening temperature of each compound.

Intended Use of the Device:

Impression Compound is intended for use as a rebasing and relining impression material as well as for general impressions including, but not limited to dentures, root surfaces and posts.

Substantial Equivalence:

Impression Compound is substantially equivalent to another legally marketed device in the United States. *Impression Compound* functions in a manner similar to and is intended for the same use as *ISO Functional*, currently marketed by GC America Incorporated.

An In Vitro Cytotoxicity biocompatibility study has been completed on *Impression Compound*, which demonstrates that the material is non-cytotoxic and is safe for its intended use. This 510(k) submission also includes data from bench testing used to evaluate the physical properties of *Impression Compound* compared to the predicate device, *ISO Functional*.

Based upon the biocompatibility and bench testing, the clinical performance of *Impression Compound* is deemed to be substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

SpofaDental
C/O Ms. Wendy Garman
Director, Regulatory Affairs
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

APR - 5 2011

Re: K110378
Trade/Device Name: Impression Compound
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: January 10, 2011
Received: January 12, 2011

Dear Ms. Garman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'for' followed by a stylized signature.

Anthony D. Watson, B.S., M.S., M.B.A.
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110378

Device Name: *Impression Compound*

Indications For Use:

Impression Compound is intended for use as a rebasing and relining impression material, as well as for general impressions including, but not limited to dentures, root surfaces and posts.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CORH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
infection Control, Dental Devices

510(k) Number: K110378

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